IN THE HIGH COURT OF JUDICATURE AT MADRAS

DATE: 15.3.2002

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THE HONOURABLE MR. JUSTICE V.S.SIRPURKAR

W.P. NO. 409 of 1996

Madras Pharmaceutical Whole
Salers Association rep. by
its Hony. Secretary
Mahaveer M. Sethia,
129, Nyniappa Naicken Street,
Madras-600 003. Petitioner

Vs.

1.Union of India,
Ministry of Health and
Family Welfare,
Department of Health,
Nirman Bhavan,
New Delhi-110 011.

2.The Drug Controller (India),
Directorate General of
Health Services,
Government of India,
Nirman Bhavan,
New Delhi-110 011. Respondents

Petition under Article 226 of the Constitution of India
praying to issue a Writ of Declaration as stated therein.

For petitioner :: Mr.B.T.Seshadri

For respondents :: Mr.K.Kumar, ACGSC

: O R D E R
The petitioner challenges in this writ petition the amendment to Rule 65 of the Drugs and Cosmetics Rules, 1945. Rule 65 deals with the condition of licences in Forms 20, 20-A, 20-B, 20-F, 20-G, 21 and 21-B. Rule 65 suggests that licences in Forms 20, 20-A, 20-B, 20-F, 20-G, 21 and 21-B shall be subject to the following general conditions:-

Conditions (1) to (4) not relevant.
"(5)(1) Subject to the other provisions of these rules the supply of a

drug by wholesale shall be made against a cash or credit memo bearing the name and address of the licensee and his licence number under the Drugs and Cosmetics Act, in which the following particulars shall be entered--
(a) the date of sale;
(b) the name, address of the licensee to whom sold and his sale licence number. In case of sale to an authority purchasing on behalf of Government, or to a hospital, medical, educational or research institution or to a Registered Medical Practitioner, for the purpose of supply to his patients the name and address of the authority, institution or the Registered Medical Practitioner, as the case may be;
(c)the name of the drug, the quantity and the batch number;
(d) the name of the manufacturer;
The following sub-clause was inserted by GSR 496(E), dated 9.6.1995 with effect from 9.6.1995.
(e) the signature of the competent person under whose supervision the sale was effected."
It is this addition which has irked the petitioner, which is an association of wholesale dealers to file this petition. The main stay of the challenge to the constitutionality or as the case may be the validity of the rule is that the said rule is unreasonable and therefore, does not stand the acid test of Article 14 of the Constitution. The argument is also that the rule is not in conformity with or has no nexus with the object of the Act.
2. Learned counsel appearing on behalf of the Central Government has opposed the petition on the ground that the object of the amendment is itself laudable. He points out that there is nothing wrong if the person who is controlling the business is asked to put his signature on the document of sale. It is also pointed out that it is only in order to curb the dealing in the spurious drugs that rule is introduced.
3. Learned counsel appearing on behalf of the petitioner took me extensively through the rule and also invited my attention to the proviso to Rule 64 in order to show that the competent person was defined in that proviso. The proviso runs as under:-
"Provided further that in respect of an application for the grant of a licence in Form 20-B or 21-B or both, the licensing authority shall satisfy himself that the premises in respect of which a wholesale licence is to be granted or renewed are,
(i) of an area of not less than ten square metres; and
(ii) in the charge of a competent person, who-
(a) is a Registered Pharmacist, or,
(b) has passed the matriculation examination or its equivalent examination from a recognised Board with the four years' experience in dealing with sale of drugs, or
(c)holds a degree of a recognised University with one year's experience in dealing with drugs."
From this learned counsel for the petitioner urges that the licence in Form 20-B cannot be had unless the person concerned has the qualifications which are provided in the second clause of the proviso. The learned counsel is at pains to point out that if the incharge is known person as the incharge of the pharmacy, then the necessity to put the signature on every document of sale would be superfluous because in that case that would be an unnecessary condition which would be of an onerous nature to the person, who is holder of

the licence under Form 20-B.
4. The criticism of the rule is completely incorrect. In the first place, though the competent person is definied in the said proviso to Rule 64, it is not necessary that every time the business would be run by a competent person alone. It could be a case where the business could be owned by someone else to be run by a competent person by putting him incharge of the pharmacy. Now in such cases unless the further defence mechanism is set up by directing the competent person to put his signatures on the sale document, it may be difficult to trace the real culprit in case where the spurious drugs are dealt with from the pharmacy or where wrong drugs are supplied through ignorance. In fact in asking the concerned person to put his signature nothing much has been required by the concerned authorities and in my opinion a condition to put the signature of the person incharge under whose supervision the sale has been conducted cannot be even viewed as an onerous condition. All that is required by the amendment is putting the signature on the sale document signifying thereby or making it certain that the sale was made under the supervision of a particular competent person and that a correct, genuine drug was supplied during that sale under the signature of the competent person. Nothing unreasonable can be seen in this condition because it would give a protection not only to the general public against the spurious drugs or wrong drugs supplied but also to the concerned competent person. It would also ensure that the business is not dealt with in absentia. Now if the condition of putting the signature of the sale document is not observed, as per the amendment, then it would be very easy to do the business in absentia also. That precisely had to be avoided and that appears to be the intendment of the amendment. The object of Drugs Act itself suggests in its preamble that it is an Act to regulate, control of manufacture, sale and distribution of drugs. If therefore the rule is introduced in this fashion to ensure the supply of proper, genuine drugs, it cannot be said that the amendment is in any manner unreasonable much less arbitrary. The amendment has definite connection with the object of the Act. In that view, the challenge under Article 14 of the Constitution must fail and it must be held that the amdnement is a good piece of law. No other point was argued before me. The writ petition has no merits and it is dismissed with costs of Rs.3,000/-.
15.3.2002
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Website: Yes
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2.The Drug Controller (India),
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V.S.SIRPURKAR, J.

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